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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,962	08/27/2001	Michael B. Foster	RENAS/04	6998
26875	7590	01/09/2004		
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			EXAMINER LY, CHEYNE D	
			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,962

Applicant(s)

FOSTER, MICHAEL B.

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2/02 . 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traversal of Group III, claims 9-15, specie insulin-like growth factor 1, filed October 27, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The requirement is still deemed proper and is therefore made FINAL.
3. The cancellation of claims 1-8 and 16-28 has been acknowledged.
4. Claims 9-15, insulin-like growth factor 1, are examined on the merits.

SPECIFICATION

5. The title of the invention is not descriptive due to the instant title being directed to a method of optimizing hormone replacement while the instant claimed subject matter is directed a system and method for monitoring patient receiving human growth hormone. A new title is required that is clearly indicative of the invention to which the claims are directed.

INFORMATION DISCLOSURE STATEMENT

6. Documents A.R to L.S have not been considered due to said documents listed on the FORM PTO-1449 not being in the instant application. The FORM PTO-1449 has been placed in the application file, but the information referred to therein has not been considered.

CLAIM REJECTIONS - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 9-15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Burns et al. (US 5,284,133 A).
3. Burns et al. discloses a method and system for monitoring the administered dosage of human growth hormone and insulin-like growth factor in a treatment regimen directed to a patient (Abstract etc. and column 6, lines 9 and 24) as in instant claim 14.
4. A physician, pharmacist, or other authorized health care professional at an off-site location analyzes the treatment regimen history (Abstract etc.). During the patient's check-up with the physician (on-site), said physician can analyze the patient's treatment history and counsel said patient or adjusting the treatment regimen accordingly (column 11, line 65 to column 12, line 2). Patient returns to the hospital or physician's office to receive the medication (column 1, lines 34-40), as in instant claims 10-12.
5. Further, Burns et al. discloses that drug side effects (patient responsiveness to administered drug) can be mitigated by properly controlling said dosage (column 1, line 66 to column 2, line 1), as in instant claim 9.
6. The system of Burns et al. comprises a controller which communicates with a recording device and a signal device for alerting patients (Figure 2 and column 10, lines 20-32). A physician could program a computer chip with data directed to dosage and schedule (column 4, lines 51-60), as in instant claims 13 and 15.

CONCLUSION

7. NO CLAIM IS ALLOWED.
8. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located


in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

11. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
12/29/03


ARDIN H. MARSCHER
PRIMARY EXAMINER